CHR HANSEN

Chr. Hansen, Inc.
1595 MacArthur Boulevard
Mahwah, NJ 07430-3601
Telephone. 201-818-1200
800-343-4680
Fax: 201-818-2173

April 3, 2003

Hearing Clerk
Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Rooms 1061
Rockville, MD 20852

Subject: Registration of Food Facilities under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Docket no. 02N-0276).

Dear Hearing Clerk,

These comments respond to FDA's notice of proposed rulemaking published in the Federal Register February 3rd 2003, requesting public comment on a document entitled "Registration of Food Facilities Under The Public Health Security and Bioterrorism Preparedness and Response Act of 2002". Please be advised that Chr. Hansen Inc. is a manufacturer and supplier of food products subject to the proposed regulation, namely food flavors, spices, cultures, and color additives with manufacturing and distribution facilities in New Jersey, Wisconsin, Illinois, Louisiana and Florida. In addition Chr. Hansen, Inc. has facilities in Europe that manufacture and export food products subject to this proposed rule. After reviewing the proposed rule, we commend the agency for taking a reasonable approach with respect to implementing the legislation that forms the

02N-0276 C74

basis for these regulations, namely the Public Health Security and Bioterrism Preparedness and Response Act of 2002 (Public Law 107-188) signed into law June 12th 2002. Obviously, this represents and extremely important agency activity which, requires serious consideration by all food manufacturers in the United States and foreign facilities exporting food to the United States. Although Chr. Hansen Inc. supports this regulatory activity, we offer specific comments to various sections of the proposed rule described as follows:

Section 1.226: Who is Exempt from this Subpart?

The proposed rule appears to exclude foreign facilities from this registration requirement, if further processing of the food takes place in a subsequent facility. The agency goes on to explain that de minimis activity in a subsequent facility does not eliminate the need to register the first facility where this de minimis activity equates to applications of labels or other similar de minimis activity. We believe the agency needs to further elaborate and specify other types of activities that would also relate to de minimis activities e.g. blending, seiving, particle size distribution, re-packaging or other activities that may comprise de minimis activities. If these issues are not resolved many more facilities may need to register than FDA intends under these proposed rules.

Section. 1.232: What Information is Required in the Registration?

The above described section of the proposed regulation prescribes information required or useful for FDA to enable registration of the facility specifically, paragraph (d) states the need for "...all trade names the facility uses". While it is true that all manufactures of food products utilize trade names in associated with the sales of their products, it remains difficult to understand the significance of trade names verses actual products associated with these trade names. Furthermore as discussed under section 1.234, which requires amendment of registration for changes occurring in the registration status of the facility, there is a need to define whether or not changes in trade names will require amendments of facility registrations. What language currently means is that if a firm decided to change a trade name or develop a new trade name for a product there would be a need to amend the registration for that facility within 30 days in accordance with section 1.234. This interpretation of this proposed rule could create endless amendments to facility registrations unless some definition of significant change is developed in the final rule.

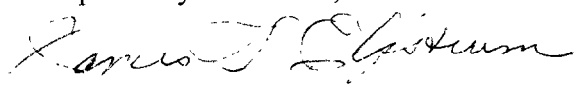
What is recommended to overcome this defect in the proposed regulation is that the agency needs to define major and minor changes that would result in the need to amend facility registrations to reflect these changes. We believe the addition of a new trade name assigned to a product in a facility manufacturing many products should not automatically trigger the need to amend, within 30 days, the facility registration. Similarly subpart (e) of section 1.233 requires food products categories be designated

for each registered facility. As stated previously, if a facility defines the need to produce a product in a new food product category presumably this would require an amendment of the facility registration.

We, therefore, strongly urge the agency to define to the greatest extent possible, conditions relating to significant change factors that would require amendments to a facility registration. Although the act doesn't require annual registrations of facilities, we believe that it would appropriate to require annual amendment of facilities registrations if minor changes occur during a calendar year to keep all facilities updated. This could be done on a rolling calendar year basis, such that the impact on FDA activities would be minimized to accommodate these rolling annual changes to facilities registrations.

Chr. Hansen appreciates this opportunity to provide comment to the agency with respect to facility registration requirements and looks forward to the publication of a final rule.

Respectfully Submitted,



James T. Elfstrum
Chr. Hansen, Inc.
Vice President
Legal & Regulatory Affairs
201-808-4118
jim.elfstrum@chr-hansen-us.com

lmw/JE